U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

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December 19, 2022

The Honorable Patty Murray
Chairwoman
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Bobby Scott
Chairman
The Honorable Virginia Foxx
Ranking Member
Committee on Education and Labor
House of Representatives

Subject: *Office of Personnel Management; Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, Centers for Medicare & Medicaid Services: Prescription Drug and Health Care Spending*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Office of Personnel Management (OPM); the Department of the Treasury, Internal Revenue Service (IRS); the Department of Labor, Employee Benefits Security Administration (EBSA); and the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) (collectively, the Agencies) entitled "Prescription Drug and Health Care Spending" (RINs: 3206-AO27, 1545-BQ10, 1210-AC07, 0938-AU66). We received the rule on December 6, 2022. It was published in the *Federal Register* as interim final rules with request for comment (IFR) on November 23, 2021. 86 Fed. Reg. 66662. The effective date is December 23, 2021.

According to the Agencies, this document sets forth an IFR to implement provisions of the Internal Revenue Code (the Code), the Employee Retirement Income Security Act (ERISA), and the Public Health Service Act (PHS Act), as enacted by the Consolidated Appropriations Act, 2021 (CAA). *See generally* Pub. L. No. 116-260, 134 Stat. 1182 (Dec. 27, 2020); Pub. L. No. 93-406, 88 Stat. 829 (Sept. 2, 1974); Act of July 1, 1944, ch. 373, 58 Stat. 682. The Agencies stated that this IFR is applicable to group health plans and health insurance issuers offering group or individual health insurance coverage, and it adds provisions to existing rules under the Code, ERISA, and the PHS Act. The Agencies also stated that the IFR implements provisions of the Code, ERISA, and the PHS Act that increase transparency by requiring group health plans and health insurance issuers in the group and individual markets to submit certain information about prescription drugs and health care spending to the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury. The Agencies stated further that they are issuing this IFR with largely parallel provisions that

apply to group health plans and health insurance issuers offering group or individual health insurance coverage. Lastly, the Agencies stated that OPM is also issuing interim final rules that require Federal Employees Health Benefits carriers to report information about prescription drugs and health care spending in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). The 60-day delay in effective date can be waived, however, if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. §§ 553(b)(3)(B), 808(2). The Agencies stated that the CAA requires plans and issuers to begin submitting the required prescription drug and health care spending information by December 27, 2021. In recognition of stakeholders' concerns about the feasibility of meeting CAA's statutory deadline, the Agencies also stated that they are exercising their discretion not to initiate enforcement actions against plans or issuers that submit data for the 2020 and 2021 reference years by December 27, 2022. Accordingly, the Agencies stated further that regulations must be published and available to the public well in advance of the December 27, 2022, enforcement date for the initial data collection. For these reasons, the Agencies assert that it would be impracticable and contrary to the public interest to delay putting the provisions of the IFR in place until a full public notice and comment process has been completed. Likewise, for these reasons, the Agencies also stated that there is good cause to waive the delay in effective date for the IFR.

Enclosed is our assessment of the Agencies' compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Oluwafunmilayo A. Taylor
Chief, Publications and Regulations Branch, Legal Processing Division
Department of the Treasury

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
OFFICE OF PERSONNEL MANAGEMENT;
DEPARTMENT OF THE TREASURY, INTERNAL REVENUE SERVICE;
DEPARTMENT OF LABOR, EMPLOYEE BENEFITS SECURITY ADMINISTRATION;
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"PRESCRIPTION DRUG AND HEALTH CARE SPENDING"
(RINS: 3206-AO27, 1545-BQ10, 1210-AC07, 0938-AU66)

(i) Cost-benefit analysis

The Office of Personnel Management; the Department of the Treasury, Internal Revenue Service (IRS); the Department of Labor, Employee Benefits Security Administration; and the Department of Health and Human Services, Centers for Medicare & Medicaid Services (collectively, the Agencies) prepared an accounting statement for this interim final rule with request for comment (IFR). The Agencies stated that they were unable to quantify all benefits, costs, and transfers associated with the IFR but have sought, where possible, to describe these non-quantified impacts. The Agencies estimate the annualized monetized cost imposed by the IFR to be $363.63 million in 2021 dollars at a 7 percent discount rate and $361.09 million at a 3 percent discount rate for a period covering 2021 through 2025. The Agencies also noted several qualitative benefits, which include, among other things, increased transparency about prescription drugs and health care spending and the potential to promote more competitive health care markets. The Agencies also provided a list of one-time costs as a result of the IFR, which include, but are not limited to, costs to issuers, Federal Employees Health Benefits (FEHB) carriers, third-party administrators, and pharmacy benefit managers (PBMs) to design, develop, implement, operate, and maintain needed internet technology systems changes. Lastly, the Agencies stated that there is the potential for transfers from providers, facilities, pharmaceutical manufacturers, and PBMs to plans, issuers, and FEHB carriers if plans, issuers, and FEHB carriers are able to achieve greater negotiating power due to improved understanding of prescription drug costs.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603–605, 607, and 609

According to the Agencies, this IFR was not preceded by a general proposed rule, and thus the requirements of the RFA do not apply.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

According to the Agencies, this IFR was not preceded by a general proposed rule, and thus the requirements of the Act do not apply.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

According to the Agencies, section 9833 of the Internal Revenue Code (the Code), section 734 of the Employee Retirement Income Security Act (ERISA), and section 2792 of the Public Health Service Act (PHS Act) authorize the Secretaries of the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services, to promulgate any interim final rules that they determine are appropriate to carry out certain provisions of these laws. The Agencies stated that, consistent with these authorities, they determined that it was appropriate to issue this IFR to enable regulated entities sufficient time to design processes and systems necessary to comply with statutory requirements.

Additionally, the Agencies have determined that it would be impracticable and contrary to the public interest to delay putting the provisions of the IFR in place until a full public notice and comment process has been completed. The Agencies stated that the CAA requires plans and issuers to begin submitting the required prescription drug and health care spending information by December 27, 2021. In recognition of stakeholders' concerns about the feasibility of meeting CAA's statutory deadline, the Agencies also stated that they are exercising their discretion to not initiate enforcement actions against plans or issuers that submit data for the 2020 and 2021 reference years by December 27, 2022. Accordingly, the Agencies stated further that regulations must be published and available to the public well in advance of the December 27, 2022, enforcement date for the initial data collection. For these reasons, the Agencies assert that it would be impracticable and contrary to the public interest to delay putting the provisions of the IFR in place until a full public notice and comment process has been completed.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

The Agencies determined that this IFR contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB). The Agencies stated that they submitted emergency review requests for three new ICRs and requested approval by the effective date of this IFR. The Agencies estimate the total annual burden hours of the ICRs to be 1,684,080 and the total cost to be $230,201,016.

Statutory authorization for the rule

The Agencies promulgated this final rule pursuant to sections 8910 and 8913 of title 5; sections 7805 and 9833 of title 26; sections 1002, 1135, 1182, 1185d, and 1191a–1191c of title 29; and sections 300gg-92 and 300gg-120 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

The Agencies determined that the IFR is economically significant under the Order and submitted it to OMB for review.

Executive Order No. 13132 (Federalism)

The Agencies determined that the IFR does not impose direct costs on states or preempt state laws. Additionally, the Agencies stated that they consulted with the states and attempted to balance the states' interests in regulating health insurance issuers with the need to ensure

transparency in the prescription drug and health care market and collect data on a consistent basis in order to inform nationwide analyses.